UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,538	12/28/2001	Stephen D. Pacetti	50623.149	3811

7590 10/03/2007

Squire, Sanders & Dempsey L.L.P.
Suite 300
One Maritime Plaza
San Francisco, CA 94111

EXAMINER	
CAMERON, ERMA C	
ART UNIT	**PAPER NUMBER**
1762	

MAIL DATE	DELIVERY MODE
10/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/040,538
Filing Date: December 28, 2001
Appellant(s): PACETTI ET AL.

Jeffrey Talkington
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 7/3/2007 appealing from the Office action mailed 1/5/2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is substantially correct. It is noted that claim 61 is withdrawn, as applicant has stated in the Status of Claims on page 2.

For independent claim 54, see in particular, 8:12-14 and 10:1-5, and also 3:17-4:21.

For independent claim 73, see in particular, 8:12-14 and 3:17-4:21.

(6) Grounds of Rejection to be Reviewed on Appeal

NEW GROUND(S) OF REJECTION

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows:

The 103(a) rejection over Ding et al (US 6,358,556) in view of You et al (US 6,407,009) has been slightly modified, setting forth a new grounds of rejections of the same claims recited by Appellant, over the same references.

(7) Claims Appendix

A substantially correct copy of appealed claims appears on page 20-27 of the Appendix to the appellant's brief. The minor errors are as follows: claims 7, 12, 14, 37-40, 42-43, 47 and 61-70 are withdrawn, as applicant has noted in the Status of Claims on page 2.

(8) Evidence Relied Upon

6,395,326	Castro et al	5-2002
6,358,556	Ding et al	3-2002
6,407,009	You et al	6-2002

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

a) Claims 1-6, 11, 13, 17-19, 21-24, 33-36, 44, 46, 48-54, 57-60 and 71-72 are rejected under 35 U.S.C. 102(e) as being anticipated by Castro et al. (US 6,395,326).

Castro et al. discloses a method of coating implantable, expandable stents with a coating composition comprising a solvent, polymer, and active agent (col. 12, line 21 – col. 14, line 41). Castro et al. discloses that dimethylacetamide may be used as the solvent in its coating composition (col. 13, lines 1-10). Dimethylacetamide is not considered volatile according to the invention and has a vapor pressure of less than 17.54 Torr (1.5 Torr at 20 C). Castro et al. teaches coating the stents by using a dispenser having a nozzle, which may be an ink-jet head (col. 8, line 59), through which the composition is delivered, which meets the limitation of spraying. Castro et al. also teaches that a heating assembly 52 is used for controlled drying of the coating (Figure 5A, col. 11, lines 11-62). Heating assembly 52 comprises heating nozzle 56 which directs heat at the coated stent to induce evaporation of the solvent, as disclosed in col. 18, lines 1-12. Since the solvent used by Castro has a vapor pressure of less than the claimed amount and the heat used by Castro will increase the evaporation of the solvent, the second of the two alternative claim requirements is met. Heating assembly also comprises a heat conduit 54 to conduct heat from 60, which is both a control system and heat source, and through an orifice 58 to deliver heat. The orifice 58 can range in size from 50 – 300 microns in diameter, depending on

the area to be heated (col.11, lines 17-53). Both the heating and coating operations are controlled by CPU (col. 11, lines 43-53).

With respect to claims 3, 33, 44 and 52, which require directing gas simultaneous with applying the coating composition, it is noted that Castro et al. teaches that the heating assembly may follow the coating pattern on the prosthesis (col.11, line 54 – col.12, line 18; col. 18, line 48 – col. 19, line 3), thus meeting the limitations of the claims.

As to claim 5, Castro et al. discloses that the polymer in the coating solution may be ethylene vinyl alcohol copolymer (col. 12, line 63), and the solvent may be dimethylacetamide as discussed above.

As to claims 6, 50 and 59, Castro et al. teaches use of paclitaxel or docetaxel as the active agent in the coating solution in col. 14, lines 1-2.

As to claims 17-18, 34, 51 and 52, the stent of Castro et al. is rotated and moved linearly along its axis during delivery of the coating solution to the device (col. 16, lines 1-11).

As to claim 19, Castro et al. teaches that the stent may be expanded during deposition (col. 7, line 53).

As to claims 21, 46 and 57, the heat from heat source 60, fed into conduit 54 and into heating nozzle 56 would necessarily be heated air or some other heated gas because heat source 60 is remote from the nozzle or stent and the heat must flow from the heat source 60 through the conduit 54 to nozzle 56 (col. 11, lines 35-62) for the purpose of drying.

As to claim 22, it is noted that the temperature of the implantable device will necessarily be increased (above atmospheric temperature) at least a little bit during the heating/drying of the coating composition by heat supplied by heat source 60. In addition, in some embodiments, the

stent/coating is heated after or cured after the coating is applied, thus meeting the limitations of claim 22 (col. 18, lines 1-12).

As to claim 24, tetrahydrofuran is one of the solvents used (col. 13, lines 1-9). THF has a boiling point of 66 degrees C. The heat applied to the coating can be as low as 35 degrees C (col. 18, line 43), thus meeting the limitation of claim 24.

As to claim 33 and the limitation of not affecting the direction of the coating spray, Castro et al. teaches that the heating nozzle may follow the coating dispenser, thus meeting the limitation that the heating nozzle not interfere with the coating process (col. 11, lines 54-62; col. 18, lines 48-col. 19, line 3). In addition, one of skill in the art would set up a coating and heating operation so as to not interfere with each other.

b) Claims 9-10, 15-16, 20, 25-26, 41, 45, 55, 56 and 73-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castro et al (6,395,326).

Castro et al. is applied for the reasons discussed above.

As to claims 9-10, Castro et al. teaches that nozzle 26 is positioned over or in contact with strut 68 of the stent (col. 16, lines 50-51), and that the dispenser may be an ink-jet head, which is a type of spraying device (col.8, line 59). Castro et al. is silent with regard to the exact distance above the stent, or the flow rate of coating material applied to the stent.

With respect to claim 15, Castro et al. is also silent with regard to the flow rate of the heating air applied to dry the coating.

With respect to claims 41 and 55, Castro et al. is silent with regard to the rotation speed of the stent.

These are all result-effective variables depending upon the particular coating solution used, the size and shape of the stent being coated, the desired thickness of the coating, etc. It is well settled that determination of optimum values of cause effective variables such as these process parameters is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

As to claim 16, Castro et al. teaches that the heat may be applied to the entire outer surface of the prosthesis or to discrete regions, and thus appears to be blowing heated air directly onto the prosthesis (col. 11, lines 35-42).

As to claims 20, 45, 56, 73, 74 or 78, Castro et al. uses the inert gas nitrogen as part of the air that flows from heat source 60 to the stent surface.

As to claims 25, 76 and 77, Castro et al. teaches heat at 35-100 degrees C delivered by nozzle 56 (col. 18, lines 34-47). This overlaps with applicant's claimed temperatures.

As to Claim 26, Castro et al. teaches that the coating composition may be heated before being deposited (col. 3, lines 23-27).

As to claim 75 to argon, the heated gas of Castro et al would be inclusive of argon, depending on the needs of the coating composition that is being applied.

NEW GROUNDS OF REJECTION

c) Claims 1-6, 9-11, 13, 15-26, 33-36, 41, 44-46, 48-49, 51-58, 60 and 71-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al (6358556) taken in view of You et al (6407009).

Because this rejection has been modified to rely upon the room temperature ventilation, instead of air brush, the following is being set forth as a new grounds of rejection.

Ding et al. teaches spraying a coating composition of polymer, solvent, and drug on a radially rotating stent, preferably when the stent is in an expanded state (col. 3, lines 15-58). Ding et al. uses an evaporative solvent such as THF with a relatively high vapor pressure (col. 6, line 55 – col. 7, line 35). The vapor pressure of THF is greater than 17.54 Torr at ambient temperature (129 Torr at 20 C). The coating is exposed to room temperature ventilation for solvent evaporation (col. 3, lines 59-61). The object is to cover the entire surface of the stent with a conformal coating of relatively thin layers (col. 3, lines 15-58).

Regarding claims 3, 13, 16, 23, 33, 44 and 52 where simultaneous (with application of coating) directing of gas or blowing gas directly onto the stent is required, the room temperature ventilation of Ding et al. would be operating while the coating is being applied, and is thus simultaneous with the coating operation, and the ventilation blows onto the stent, at least to some extent.

Regarding claim 35, the spraying operation may be computer controlled (col. 8, lines 12-14).

As to claim 5, Ding et al. generally discloses that "thermoplastic elastomers in general" may be used as the polymeric material in its coating compositions (col. 4, line 59). It would

have been obvious to one having ordinary skill in the art to have selected a specific thermoplastic elastomer, such as ethylene vinyl alcohol copolymer, from the broad class taught by Ding et al. because a specific member of the broad class would be expected to function in a similar and successful manner of providing hydrophobic biostable elastomeric coating properties to a stent. Further it would have been obvious to have substituted one solvent for another with the expectation of equivalent results since the solvent merely evaporates from the coating after application.

As to claim 6, Ding et al. generally teaches the use of a wide range of drugs as the biologically active species in the composition of his invention (col. 4, line 65 – col. 5, line 9). While Ding et al. does not specifically teach the use of paclitaxel, docetaxel or rapamycin as the bioactive agent, it is noted that these drugs are well-known in the medical coating art. It would have been obvious to one having ordinary skill in the art to have selected a specific drug, such as paclitaxel, from the broad class of drugs taught by Ding et al. because a specific member of the broad class would be expected to function in a similar and successful manner of providing bioactive properties to a stent.

As to claims 9-10, Ding et al. is silent with regard to the distance from the tip of the sprayer to the substrate and the flow rate of coating material. These are known result-effective variables depending upon the desired thickness, viscosity of coating material, exact type of sprayer used, etc. It is well settled that determination of optimum values of cause effective variables such as these process parameters is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Regarding claims 41 and 55, Ding et al. teaches rotating the stent at 30-50 RPM (col. 8, lines 5-14), which meets the limitation of >0.1RPM.

Ding et al. lacks a teaching that the temperature of the directed gas is adjusted to control the rate of evaporation.

It is very well known in the coating art to control the evaporation of solvent from a coating material (either to speed up evaporation or slow down evaporation) by adjusting the temperature of the atmosphere surrounding the coating to avoid bubbling, non-uniformity, or the like. Evaporation rate impacts coating integrity, especially on rotating substrates. You et al. is cited as an exemplary teaching of such a concept (col. 5, line 37 to col. 6, line 6; col. 6, line 40 to col. 7, line 8; and col. 7, line 53 to col. 8, line 10). You et al. is directed to a method of spin-on coating with liquids which comprise polymer in volatile solvent, similar to Ding.

You et al. teaches that, in order to control the rate of evaporation of solvents, the temperature inside a deposition chamber 103 can be decreased during deposition using cooled inert bias gas 126 (nitrogen, helium or argon) or can be increased by heaters 136 (col. 5, line 37 - col. 6, line 6). If the chamber is cooled, the rate of evaporation of volatile solvents is reduced, and if the chamber is heated, solvents that are not as volatile will experience a higher rate of evaporation (col. 6, line 65 – col. 7, line 8; col. 7, line 53 – col. 8, line 11; col. 18, line 1 – col. 19, line13). The object is to create even, uniform, planar coatings without gaps (col. 2, line 65 – col. 3, line 43).

It would have been obvious to have incorporated the teachings of You et al. into the process of Ding et al. by coating in the presence of blown temperature-controlled gas. It would have been obvious to one of ordinary skill in the art to use cooling for highly evaporative

solvents to slow evaporation, as is taught by You et al, in the method of Ding et al to provide Ding et al with a temperature of for his ventilated gas sufficient slow evaporation and enhance coating uniformity, as desired by both Ding and You. One skilled in the art would have expected successful results since both references are similarly related to the deposition of polymeric coatings in a solvent onto a rotating substrate, and evaporation of the solvent in a controlled fashion, in order to achieve even, uniform coatings.

As to claim 13, it is noted that the flow of chilled air in a deposition chamber, as in the process of Ding et al. in view of You et al., would necessarily comprise air/gas which flows at an angle relative to the direction of the spray.

As to claim 15, the flow rate of the chilled air/gas would be determined through routine experimentation depending upon the degree of cooling needed.

As to claim 22, it is noted that the temperature of the implantable device will necessarily be changed due to the presence of heaters or chilled air/gas.

As to claim 25, the temperature of the chilled air/gas may be below room temperature, for instance, -20 C (col. 7, line 52 - col. 8, line 11).

Regarding claims 76 and 77, You et al. teaches that the temperatures used will depend on the solvent and coating material, but gives as an example a solvent evaporation temperature of 150 C. It would have been obvious to one of ordinary skill in the art to have optimized the solvent evaporation temperature through no more than routine experimentation because of the teaching of You et al. that the temperature will be selected depending on the solvent.

(10) Response to Argument

The numbering corresponds to applicant's numbering of arguments in the Appeal Brief.

i) 102(e) over Castro et al

1) The examiner withdraws an argument based on "bursts of air pressure" (paragraph 5 from the 1/5/2007 office action), and apologizes for any confusion that it may have caused.

2), 5) and 6) The applicant has argued that the heat may be from another source, other than a heated gas and gives, as an example, a glowing, charged pin. However, Castro et al. teaches a heat source/controller 60 that is remote from the heating nozzle 56, and a conduit 54 to take that heat to the heating nozzle 56 (col. 11, lines 17-53). It is immediately envisaged that it would take the motion of a fluid to get from the remote heat source 60 to the heating nozzle 56. A glowing pin in the heating nozzle orifice would not derive its heat from a heat source nor would said heat travel via the conduit.

3) The applicant has argued that Castro et al. does not teach the temperature adjustment of claim 1. However, all that is required of claim 1 is that, in one of two *alternatives*, if the solvent has a VP less than 17.54 Torr, then the temperature of the gas is adjusted to increase the evaporation of the solvent. Castro et al. discloses dimethylacetamide which has a VP less that 17.54 and heat of 35-100 degrees C applied to the coating composition (col. 13, lines 1-10; col. 18, lines 34-47), thus satisfying the limitations of claim 1. Claim 1 requires only one of two alternative embodiments. In so much that Castro selects a temperature, he is adjusting it.

4) The applicant has argued that the nozzle could house a heating coil or glowing pin, and thus supply heat to the stent coating. However, 60 of Figure 5A may be both a heat source and heat controller. Because 60 is remote from the heating nozzle 56, it is impossible for the heat source to be in the nozzle under these circumstances (col. 11, lines 43-53).

The applicant has also argued that a flow of gas is harder to regulate than heat from a heating pin. This argument is unpersuasive as one of ordinary skill in the art would immediately envisage the use of heated air flowing from a heat source via a conduit, through the outlet nozzle to evaporate solvent. One of ordinary skill in the art would have had the skill to adjust the nozzle diameter to effect the desired amount of control (note Castro's micro-sized orifice diameter, above, would necessarily provide discrete control of air flow as required by Castro). Additionally, the argument above shows that since 60 is a remote heat source, Appellant's contrived glowing pin scenario is not possible.

7) The Declarations under 37 CFR 1.132 filed 10/13/2006 are insufficient to overcome the rejection of claims 1-6, 9-11, 13, 15-26, 33-36, 41, 44-46, 48-60 and 71-78 based upon Castro et al (6395326) because: the declarations offer no substantive reasons for their statements that 6395326 does not teach each of the independent claims, and are merely opinion. The inventors have not disclosed which aspects of the independent claims 1, 23 and 54 are not described by Castro et al.

ii) 103(a) over Castro et al

The examiner has addressed each of the arguments in 1, 3, 5 and 8 in a) above.

The examiner has addressed each of the arguments in 2, 4, 6, 7 and 9-11 in b) above.

iii) 103(a) over Ding et al in view of You et al

1) Regarding the air brush taught by Ding, the examiner is no longer relying on the air brush but rather on the evaporation of solvent with room temperature ventilation (col. 3, lines 59-61) to combine with You.

2) Ding et al teaches THF as a solvent (col. 6, lines 55-67), which has a vapor pressure of 129 Torr at 20 C, thus meeting the limitation of Claim 1.

3) Regarding directing or blowing gas "directly" (claims 1, 23 and 73): It is the examiner's position that both Ding et al and You et al teach blowing a gas directly. Ding teaches evaporating solvent with room temperature ventilation (col. 3, lines 59-61), which would inherently blow onto the medical device; otherwise, the room temperature ventilation would not be assisting in the evaporation of solvent, as Ding et al says is happening. Regarding You et al, applicant's argument is relying on one method of cooling the chamber, i.e. adiabatically. However, You et al suggests several methods that can be used to cool the chamber, including coolers 140 using cold air (col. 5, lines 48-54). Figure 1a shows the cooler 140 positioned over the wafer location on the chuck 104.

4) , 5), 6) and 7) The applicant has argued that there is no motivation to combine Ding et al and You et al. It is the examiner's position that a) both references teach coating onto spinning/rotating surfaces, b) both references teach controlling evaporation of solvents in a coating process, and c) both references teach controlling evaporation to achieve even coatings (Ding et al: the coating should conform to and cover the entire surface, and be relatively thin (col. 3, lines 15-61); You et al: the coating should be even, uniform and planar and not have gaps (col. 2, line 65-col. 3, line 43)).

Thus, even though the technologies are different, the processes and objectives are aligned, and thus there is motivation to combine Ding et al and You et al.

The Supreme Court of the United States has recently explained that "[w]hen a work is available in one field, design incentives and other market forces can prompt variations of it, either in the same field or ***in another***." KSR Int'l Co. v. Teleflex Inc., 82 USPQ2d 1385, 1389 (2007). The Court stated that "if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill." Id. Thus, a factfinder must ask "whether the improvement is more than the predictable use of prior-art elements according to their established functions." Id.

In this case, You teaches manipulating temperature to achieve desired evaporation rates during the coating of a wafer. You, like Ding, teaches evaporation of solvent from rotating substrates and further teaches the desirability of conformal or uniform coatings. Given these teachings, one of ordinary skill in the art would have been led to control the evaporation of

solvent in Ding by manipulating temperature, as shown in You, in order to obtain conformal or uniform coatings on the stent.

That You is directed to the coating of wafers, while Ding is directed to coating of stents, does not defeat the examiner's combination. The two separate tests for determining whether a prior art reference is analogous are as follows: (1) whether the art is from the same field of endeavor, regardless of the problem addressed; and (2) if the reference is not within the inventor's endeavor, whether the reference is reasonably pertinent to the ***particular problem with which the inventor is involved***. In re Bigio, 381 F.3d 1320, 1325, 72 USPQ2d 1209, 1211-12 (Fed. Cir. 2004). Here, the inventor is concerned with control of evaporation of solvent to effect a smooth coating. As in the present invention, You is also concerned with controlling evaporation rates to effect a uniform coating. Because You's purpose is identical or substantially identical to applicant's disclosed purpose, You constitutes analogous art and can therefore be combined with Ding. One of ordinary skill in the art could have implemented the claimed variation of You in the method of Ding with *predictable* results.

The applicant has argued in 7) that application of gas to a stent would not be a more controlled drying step than oven drying. And yet that is exactly what Ding teaches – evaporating the solvent by ventilation (col. 3, lines 59-61).

As to Appellant's arguments that it would not have been obvious to enhance uniformity, prevent cracking, or control drying using the teachings of You in the method of Ding because Ding is not taught to suffer from any coating problems, Examiner notes that inventions are ripe for improvement. Examiner also notes that enhancing evaporation rate and enhancing coating

quality in terms of enhancing uniformity or preventing gaps or cracks are all inter-related in terms of motivation.

8) The applicant has argued that the references teach away from each other. The examiner disagrees. Ding et al teaches that the gaps of the substrate must not be filled with coating material, and You et al teaches "spin-on layers with better gap filling properties", as the applicant has correctly pointed out. However, over the surface of the stent, as opposed to the gaps between the struts of the stent, Ding et al wants a coating that conforms to the surface of the stent and covers the entire surface of the stent (col. 3, lines 48-58), in other words, the same type of even, complete and no-gap coating that You et al wants to achieve. On both types of substrates, there is an even, no-gap coating.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

This examiner's answer contains a new ground of rejection set forth in section **(9)** above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer exercise one of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

Respectfully submitted,

Erma Cameron

Erma Cameron

ERMA CAMERON
PRIMARY EXAMINER

A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:

GREGORY MILLS
QUALITY ASSURANCE SPECIALIST

Conferees:

Tim Meeks

TIMOTHY MEEKS
SUPERVISORY PATENT EXAMINER

/Jennifer Michener/

Quality Assurance Specialist, TC1700

Jennifer K. Michener

Erma Cameron

ERMA CAMERON
PRIMARY EXAMINER